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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,099	03/27/2001	Jan G.J. van de Winkel	MXI-170	2545

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EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	13

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,099	VAN DE WINKEL, JAN G.J.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 2-5, 13-24 have been cancelled.

Claim 1 has been amended.

2. Claims 1, 6--12 are pending and under examination.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

4. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

5. The rejection of claims 1, 6--12 under 35 U.S.C. 102(b) as being anticipated by Shen et al (WO 98/23646, published 6/98, IDS #4) as evidenced by Monteiro et al (J. Exp. Med 171:597-613, 1990) and the specification is withdrawn in view of the new grounds of rejection.

6. The rejection of claims 1, 6-7, 11-12 under 35 U.S.C. 102(e) as being anticipated by van de Winkel (U.S. Patent 6,111,166, filed 6/27/97) and as evidenced by Monteiro et al (J. Exp Med 171:597-613, 1990) and the specification is withdrawn in view of the amendments to the claims.

7. The rejection of claims 1, 6-12 under 35 U.S.C. 103(a) as being unpatentable over van de Winkel (U.S. Patent 6,111,166, filed 6/27/97) as evidenced by Monteiro et al (J. Exp. Med. 171:597-613, 1990) and the specification, and further in view of Morton

et al (Critical Reviews in Immunology 16:423, 1996, IDS #6) is withdrawn in view of the amendments to the claims.

Response to Arguments/NEW GROUNDS of rejection

Claim Rejections - 35 USC § 103

8. Claims 1, 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shen et al (WO 98/23646, published 6/98, IDS #4) as evidenced by Monteiro et al (J. Exp. Med 171:597-613, 1990) and the specification.

The claims recite a method for eliminating a target cell or antigen from the circulatory system of a subject comprising administering a complex comprising monomeric IgA or a portion that binds to FcαRI linked to a second portion that binds a cancer target cell or antigen or bacteria, fungus, or virus, further claimed is that the method comprises administration of GM-CSF, wherein administration is by intravenous.

Shen et al teach binding agents specific for the FcαR and the binding agents triggers an Fc mediated effector cell activity such as phagocytosis (see page 1). Shen et al also teach bifunctional binding agents comprising an agent that binds FcαRI and a bacteria (see page 22) or cancer cell or antigen (see page 19-20) thereof, further is a method for eliminating cells or antigen in a subject by administration of the bispecific agent to a subject (see page 28-29) and the method further comprises adding GM-CSF which enhances the number or activity of Fcα receptors (see page 28) and the method

comprises administration intravenous (see page 29, line 35) and the binding agents bind the FcαR with the same affinity as a type of IgA which can be monomeric IgA (see page 6). As evidenced by Monteiro et al (and the specification at page 1, lines 6-8) there is only a single class of IgA Fc receptor, Fcα RI, therefore since the agent binds to Fcα RI, it would be obvious that the agent would bind to Fcα RI expressed on Kupffer cells and adding cytokine would increase the expression of the Fcα RI on Kupffer cells. Shen et al does not specifically teach that the binding agent can be monomeric IgA.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the a complex comprising monomeric IgA linked to a second antibody (a bispecific agent) for the elimination of a target cell or antigen.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the a complex comprising monomeric IgA linked to a second antibody (a bispecific agent) for the elimination of a target cell or antigen because Shen et al teach FcαRs are capable of interacting with IgA in the form of monomers and binding induces phagocytosis (see page 3, lines 28-30) and Shen et al teach that the binding agent binds with the same affinity as monomeric IgA and that the binding agent does not inhibit the binding of IgA (see page 5-6). Thus, it would have been obvious to have the binding agent be monomeric IgA linked to a second antibody because monomeric IgA would bind with the same affinity as a type of IgA and it would bind to the IgA site and perform phagocytosis.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

The response filed 4/1/03 has been carefully considured but is deemed not to be persuasive. The response states that Shen et al fails to teach or suggest the invention because the invention shows for the first time that monomeric IgA plays an important role in immunity by its interaction with FcαR expressed on liver Kupffer cells and other cells expressing FcαR (see page 8 of response). In response to this argument, Shen et al specifically teach the interaction of monomeric IgA for phagocytosis (see page 3) and as evidenced by Monteiro et al (and the specification at page 1, lines 6-8) there is only a single class of IgA Fc receptor, Fcα RI, therefore since the agent binds to Fcα RI, it would be obvious that the agent would bind to Fcα RI expressed on Kupffer cells and adding cytokine would increase the expression of the Fcα RI on Kupffer cells.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00

am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879